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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,975	06/29/2001	Mark R. Schmitt	AM100341	9267

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/895,975	SCHMITT ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6,8,10-12,14,15,17-20,22,67,74-77, 79-81, 83-85, 87, 88, 90-93, and 95- 99* is/are pending in the application.

4a) Of the above claim(s) *8, 12, 17, 74-77, 79-81, 83-85, 87, 88, 90-93, 95 and 97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,6,10,11,14,15,18-20,22,67,96,98 and 99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is acknowledged that applicant has elected with traverse the invention of Group 3 (claims 2-4, 6, 10, 11, 14, 15, 18-20, 22, 67, 96, 98 and 99 (in part)) in the reply of 11-06-06.

The traversal is on the ground that the groups have a common structural core which does not necessitate an additional separate search, and a searching burden for the Examiner. Said traversal is not found persuasive because the core of *[1,2,4]triazolo[1,5-a]pyrimidine.* Note, the current search on the elected group alone yields many hits which require undue burden in considering all compounds with various substituents. Furthermore, the proviso in claim 1 clearly indicates that the volume of prior arts on the compound could be overwhelming. Thus, combining groups would necessitate a burden of searching and examining.

Therefore, the restriction is deemed proper and made FINAL.

Claims 1, 5, 9, 13, 16, 21, 23-66, 68-73, 78, 82, 86, 89 and 94 have been cancelled.

Claims 8, 12, 17, 74-77, 79-81, 83-85, 87, 88, 90-93, 95 and 97 are withdrawn as being drawn to the non-elected subject matter.

Claims 2-4, 6, 10, 11, 14, 15, 18-20, 22, 67, 96, 98 and 99 (in part) remain fore consideration.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4, 6, 10, 11, 14, 15, 18-20, 22, 67, 96, 98 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims:

Even though variable R^1 of the elected group is directed to alkylamino, dialkylamino or NR^aR^b, the method recited in claim 2 still covers the treatment of all kinds of cancer using a large number of compounds. Thus, the scope of the treatment is unduly broad. Claims 3, 4, 6,

10, 11, 14, 15, 18-20, 22, 67, 96, 98 and 99 depend on claim 2, and thus, carry out the same unduly broad scope even though the compound's scope is more specific.

The amount of direction or guidance presented:

Regarding a method of treating cancer using compounds of the elected group, the specification does not seem to provide data to support the activity for the treatment of cancer using said compounds. Bioassays were done on various human cell lines such as: non-small cell lung carcinoma, glioblastoma, prostate carcinoma and colon adenocarcinoma. However, compounds having the amino group at the 7-position (i.e., elected compounds) do not appear to have activity (see Table 2, **compounds #231-269**). Due to the structural difference, the activity of other compounds cannot be extrapolated to those of the elected group. Thus, the specification fails to provide support for the method of treating cancer using compounds of formula I wherein R^1 is alkylamino, dialkylamino or NR^aR^b (or those of the elected group).

The state of the prior art:

Several US patents such as: **Pees et. al.** (US 6,297,251 B1), **Aven** (US 6,165,940), **Pfrengle** (US 5,994,360), show that a compound of *[1,2,4]triazolo[1,5-a]pyrimidine* substituted with an amino group at the 7-position has fungicidal activity, and not anti-cancer activity. Therefore, the state of the art does not seem to support the claimed method either.

The relative skill of those in the art:

Even with the advanced training, the skilled clinician would have to carry out extensive research to select an effective compound from the large Markush group of formula I. Not only one has to determine an IC_{50} value, but also *in-vivo* activity to establish an LD_{50}, therapeutic

index and pharmacokinetic profile for each compound. Given a large Markush group of the claimed formula I, such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary:

The pharmaceutical art has been known for its unpredictability due to various conflicting pathways, or biological factors that are sometimes genetically unique to individuals. In the instant case, compounds of the elected group do not seem to have cytotoxic activity. Thus, one skilled in the art would have to conduct both *in-vitro* and *in-vivo* assays to determine effective compounds and their appropriate dosage.

See ***Hoffman v. Klaus*** 9 USPQ 2d 1657, and ***Ex parte Powers*** 220 USPQ 925 regarding type of testing needed to support *in vivo* uses.

Note, the "how to use" requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compound if one skilled in the art would not be able to use the compound effectively without undue experimentation. See **In re Diedrich**, 138 USPQ 128; **In re Gardner et. al.**, 166 USPQ 138. Thus, where claimed compounds do not bear structures that are similar to known compounds having the same activity and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 USC 112. See **In re Moureu et. al**. 145 USPQ 452. Note, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the **full scope** of the invention without 'undue experimentation'".

Thus, given the unpredictable nature of the art, and the vast number of elected compounds, one skilled in the art will have to carry out undue experimentation to practice the method of treatment recited in the above claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tamthom N. Truong
Examiner
Art Unit 1624

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2-15-07

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